DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6008

M3824r1

WARNING LETTER

Certified Mail
Return Receipt Requested

File # 00-NWJ-38

June 5, 2000

John W. King
Owner
King Oyster Farms
8801 Berry Avenue
Port Norris, NJ 08349

Dear Mr. King:

We inspected your seafood processing facility, located at 8801 Berry Avenue, Port Norris, New Jersey from May 3-4, 2000 and found serious deviations from the Seafood Hazard Analysis and Critical Control Point or HACCP regulations (Title 21, Code of Federal Regulations, Part 123) and the regulations covering the Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food (Title 21, Code of Federal Regulations, Part 110). These deviations, described below, cause your products -- bluefish, shad, blue claw crabs, weakfish, and white perch -- to be adulterated under the Federal Food, Drug and Cosmetic Act (the Act). In addition, your products may be injurious to health, as they were repackaged under the conditions described below. The violations were:

1. Your HACCP plan for scombrotoxin-forming species (bluefish and shad) does not adequately address and control chemical hazards (histamine, in particular) at the critical control points of receiving and cooler storage *[21 CFR 123.6 & 123.8].* Your plan does not identify critical limits for histamine and does not establishing monitoring procedures for the receiving step. Harvest vessel records were not maintained or required by your HACCP plan, in the absence of controls at the receiving step. Also, you are not performing verification steps (such as thermometer calibration or quarterly histamine testing) as required.

2. Your HACCP plans for blue crab claws and white perch do not adequately address and control chemical hazards at the receiving step *[21 CFR 123.6].* In addition, you do not have documentation from harvesting vessels, indicating the area where the white perch and blue crabs were harvested and certification that the products were not harvested from unapproved waters.

3. Your firm is not adequately monitoring conditions as required under Sanitation Standard Operating Procedures *[21 CFR 123.11 & 110.35(a)]*. The quality of processing water/ice and exclusion of pests are not documented as required. Your documentation of the cleanliness of your facility is contradicted by our Investigators' visual observations. Specifically, our Investigator observed moldy residue on fly strips and on the inside surface of your product cooler. Documentation for hand-sanitizer strength consistently reported 100% (pure bleach). However, 100 ppm is the correct concentration and our Investigators observed no hand sanitizer solution dip station in use during our two-day inspection.

4. Your cooler temperature records do not represent accurate values as required *[21 CFR 123.6(c)(7)]*. For the time period February 1, 2000 through May 7, 2000, your cooler temperature records all indicate a temperature of 38°F, each temperature taken precisely at 9:00 AM, 12:00 PM, and 6:00 PM. The cooler temperature records were filled out three days in advance, and with values unsubstantiated by two facts. First, our Investigators took temperatures with calibrated thermometers in your cooler and found 47°F on May 3, 2000, at 11:00 AM. Second, live blue crabs are stored in that cooler, often for a substantial period of time and 38°F would kill the crabs. These facts demonstrate the cooler temperature is not consistently 38°F.

5. Your receiving step monitoring procedures and recordkeeping for bluefish and shad are inadequate *[21 CFR 123.6(c)(4)]*. Our Investigators observed your employee incorrectly injecting a temperature probe into bluefish, where the probe exited the fish and the sensor probe had contact with the outside air. Temperatures taken for bluefish and shad that date indicate 52°F. However, the time of death of the two products was not noted, which would demonstrate an allowable time at ambient temperature before histamine production and/or decomposition would increase to hazardous levels.

6. You do not employ an individual or have an off-site individual adequately trained in the principles of HACCP *[21 CFR 123.10]*. Such an individual is required in the assessment of hazards, development of the HACCP plan and associated procedures, and the review of monitoring records.

7. You or other employees at your firm, trained in the principles and application of HACCP, are not reviewing critical control point and monitoring records for bluefish and shad *[21 CFR 123.8(a)(3)]*.

8. Your records of cooler temperatures do not indicate the time that temperatures were taken, the initials or signature of the person performing the temperature checks, and the address of the facility where the temperatures were taken *[21 CFR 123.9(a)]*.

9. Your HACCP plans for bluefish, shad, blue crab claws, and white perch are not signed and dated *[21 CFR 123.6(d)]*.

10. Our Investigators noted several sanitation deficiencies *[21 CFR 110].* Wooden totes are used to store wet ice for packing, and the totes are in a state of disrepair. Insects and brown soil were found in the wet ice used in the packaging of whole raw bluefish, weakfish, and white perch. Packaging employees were observed smoking while harvesters were unloading their catch. The employees then began repackaging bluefish, weakfish, and white perch without washing their hands.

This letter may not list all the deviations at your facility. You, as a fresh seafood repacker, are responsible for ensuring that your processing facility operates in compliance with the Act, the Seafood HACCP regulations, and the current good manufacturing practice for human food.

You should take prompt action to correct the above deviations, as well as any other deviations you have knowledge of. Corrections should include the establishment or refinement of HACCP controls, procedures, monitoring, and training designed to prevent future violations. If you fail to promptly correct these violations, we may take further action to seize your products, enjoin your firm from operating, or criminally prosecute your firm and/or responsible individuals.

Please respond in writing within 15 days from receipt of this letter. Your response should outline the specific steps you are taking to correct the deviations. Please send your reply to the attention of Kirk D. Sooter, Compliance Officer, U.S. Food and Drug Administration, 10 Waterview Boulevard, Third Floor, Parsippany, NJ 07054. If you have any questions regarding any issue in the letter, please contact Mr. Sooter at 973-526-6008.

Sincerely yours,

Douglas I. Ellsworth
District Director